Following a pioneer study on Down Syndrome, the Jérôme Lejeune Institute initiates a new clinical trial

Professor Mara Dierssen and doctor Rafael de la Torre’s team (Barcelone) have just made public the results of one of the first clinical studies with therapeutic aims for Down Syndrome patients *. This pioneer trial has been funded partly by the Jérôme Lejeune Foundation. Carrying on with these first works, the Foundation announces the launch during the fall of a new pilot trial that the Jérôme Lejeune Institute will lead on children with Down syndrome.

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This clinical trial is an important step in the research with therapeutic goal for Down syndrome patients **. It allowed to test exploration tools (functional MRI) and evaluation ones (neuropsychological tests), useful for the future. If significant results on some neuropsychological tests were observed, neither do they allow the making of definite conclusion on the activity of the molecule EGCG in the improvement of cognitive capacities, nor do they insure of its complete safety.

Considering those results the Foundation and the Institute currently advise Down syndrome patients not to consume products based on green tea (on sale in the trade and on the web).

The Jérôme Lejeune Institute initiates a new clinical trial

The Jérôme Lejeune Institute will initiate a new pilot clinical trial in the fall of 2016 to develop this path of research. It will concern 7 to 12 years old Down syndrome children. This trial is based on the hypothesis that the administration of the EGCG to this young population with greater cerebral plasticity is likely to attain more evidential results.

This pilot study joins the axis of DYRK1A gene research. Development of treatments is a tremendous challenge, in so far as Down syndrome implies many genes. Multiple approaches are necessary.

* Safety and efficacy of cognitive training plus epigallocatechin-3-gallate in young adults with Down’s syndrome (TESDAD): a double-blind, randomised, placebo-controlled, phase 2 trial », De la Torre, Rafael et al., *The Lancet Neurology*, vol. 15, No. 8, p. 801-810

** Professor Mara Dierssen and Doctor Rafael de la Torre’s clinical trial (TESDAD Program) was conducted by the medical team of Barcelone on a group of 84 adults, carriers of Down syndrome from 16 to 34 years old. It studies the effects of the EGCG molecule (epigallocatechine gallate), extracted from green tea, on gene DYRK1A in association with a cognitive stimulation.
This gene, located on chromosome 21, is implied in growth and cerebral plasticity. Its over expression explains part of the difficulties of patients with Down syndrome. The EGCG, which is an inhibitor of DYRK1A is administrated with the intention of rebalancing the towering rate of DYRK1A in the brain of patients. This gene’s role has been highlighted in mouse models with trisomy 21 by the professors Jean Delabar and Mara Dierssen. The study hypothesizes that the diminution of the expression of DYRK1A could allow an improvement of cognitive capacities. The clinical trial TESTAD had been initiated with the support of the Jérôme Lejeune Foundation to explore this hypothesis.